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| 10/507,313      | 09/10/2004  | Tatsuro Kawamura     | 43888-333           | 4073             |

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McDermott Will & Emery  
600 13th Street NW  
Washington, DC 20005-3096

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| EXAMINER |
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MUI, CHRISTINE T

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| ART UNIT | PAPER NUMBER |
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1797

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06/20/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/507,313 | <b>Applicant(s)</b><br>KAWAMURA ET AL. |  |
|                              | <b>Examiner</b><br>CHRISTINE T. MUI  | <b>Art Unit</b><br>1797                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4,5 and 7-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7,8,11,12 and 15 is/are rejected.
- 7) ☒ Claim(s) 9,10,13 and 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments, see REMARKS, filed 07 March 2008, with respect to the rejection(s) of claim(s) 1-17 under 35 USC 102(b) and 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of USP 5,464,775 to Smith.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 4, 5, 7, 8, 11, 12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 5,464,775 to Smith (herein referred 'Smith').

6. Regarding claim 1, the reference Smith discloses a method for detecting an adulterant in urine. The method comprises of step of first taking a sample of urine and mixing it with a reagent in a specific ratio. The reagent is based on an indicator principle which gives a change or increase in absorbance when in the presence of urine. Once the reagent and urine are mixed the mixed solution will exhibit a change in absorbance, depending on the presence of the adulterant. A change in absorbance is monitored at a specific wavelength by UV-visible spectrophotometer and the optical characteristics are measured in 30 second time intervals once the two liquids are mixed to determine the presence or absence of the adulterant at a wavelength of 405 nm. Furthermore, when the urine is adulterated, the result is an increase in the absorbance when it is mixed with the reagent system in the specified ratio and the indicator will cause the mixture to increase in absorbance, depending on the presence of the adulterant or not. This inspection of the liquid is done by automatic analyzers which employ spectrophotometric means of inspection (see abstract, column 2, line 65-column 3, line 3, column 4, line 2-column 5, line 51). It is interpreted by the examiner that when the analyzer detects the absorbance of the mixed urine and reagent and indicates the increase or no change in the absorbance due to the presence or absence of the adulterant in the mixture is an indication as to whether or not the mixture is homogenously mixed or the reaction is complete. Smith does not specifically disclose a step of

obtaining  $(dS1/dt)/S1$ , but it would have been obvious to one having ordinary skill in the art at the time the invention was made to calculate the  $(dS1/dt)/S1$  value since during inspection, all of the variables, such as the absorbance measurements at 30 second intervals are recorded from the automatic analyzers to determine the change in absorbance throughout the process of mixing the urine and reagent.

7. Regarding claim 4, the reference Smith discloses the claimed invention. Smith discloses that in the instant invention, when urine which has been adulterated, resulting in an increase in absorbance, is mixed the reagent system in the prescribed ratio, the indicator will cause the sample mixture to increase in absorbance, depending on whether the adulterant is present or not (see column 4, lines 18-27). It is interpreted by the examiner that the reaction is considered to be complete when there is not any adulterant in the reagent to increase the absorbance when being analyzed.

8. Regarding claim 5, the reference Smith discloses a method for detecting an adulterant in urine. In the method of detecting gluteraldehyde adulterant in a sample of urine, an aliquot of urine is inserted into an automatic analyzer and a spectrophotometric absorbance reading is taken. The aliquot is then mixed with a reagent mixture, in a specified ratio, containing an indicator and a second spectrophotometric absorbance reading is taken and compared to the first reading. When the spectrophotometric absorbance is taken, the sample is injected into a series of three instruments where it is automatically analyzed and sample absorbance readings are taken at 405 nm at 30 second intervals. Furthermore, when the urine is adulterated, the result is an increase in the absorbance when it is mixed with the reagent system in the specified ratio and the indicator will cause the mixture to increase in absorbance, depending on the presence of the

adulterant or not. This inspection of the liquid is done by automatic analyzers which employ spectrophotometric means of inspection (see abstract, column 2, line 65-column 3, line 3, column 4, line 2-column 5, line 51). It is interpreted by the examiner that the when the analyzer detects the absorbance of the mixed urine and reagent and indicates the increase or no change in the absorbance due to the presence or absence of the adulterant in the mixture is an indication as to whether or not the mixture is homogenously mixed or the reaction is complete. Smith does not specifically disclose a step of obtaining  $(dS1/dt)/(S1-S0)$ , but it would have been obvious to one having ordinary skill in the art at the time the invention was made use the values that were obtained from the first absorbance reading and the continuous absorbance readings at 30 second intervals to calculate  $(dS1/dt)/(S1-S0)$  to determine change in optical absorbance changes over the time the urine and reagent indicator were mixing taking into account the first absorbance reading to normalize the change within the 30 second interval time that is predetermined by the specification parameters of the analyzer.

9. Regarding claim 7, the reference Smith discloses the claimed invention. Smith discloses that in the instant invention, when urine which has been adulterated, resulting in an increase in absorbance, is mixed the reagent system in the prescribed ratio, the indicator will cause the sample mixture to increase in absorbance, depending on whether the adulterant is present or not (see column 4, lines 18-27). It is interpreted by the examiner that the reaction is considered to be complete when there is not any adulterant in the reagent to increase the absorbance when being analyzed.

10. Regarding claim 8, the reference Smith discloses a method for detecting an adulterant in urine. The method comprises of step of first taking a sample of urine and mixing it with a

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reagent in a specific ratio. The reagent is based on an indicator principle which gives a change or increase in absorbance when in the presence of urine. Once the reagent and urine are mixed the mixed solution will exhibit a change in absorbance, depending on the presence of the adulterant. A change in absorbance is monitored at a specific wavelength by UV-visible spectrophotometer and the optical characteristics are measured in 30 second time intervals once the two liquid are mixed to determine the presence or absence of the adulterant at a wavelength of 405 nm. When the mixture is analyzed by the Olympus AU5000 the concentration of the mixed urine and reagent are measured at the wavelength of 405 nm with a sample volume of 10  $\mu$ L and reagent volume of 300  $\mu$ L. Furthermore, when the urine is adulterated, the result is an increase in the absorbance when it is mixed with the reagent system in the specified ratio and the indicator will cause the mixture to increase in absorbance, depending on the presence of the adulterant or not. This inspection of the liquid is done by automatic analyzers which employ spectrophotometric means of inspection (see abstract, column 2, line 65-column 3, line 3, column 4, line 2-column 5, line 51). It is interpreted by the examiner that the when the analyzer detects the absorbance of the mixed urine and reagent and indicates the increase or no change in the absorbance due to the presence or absence of the adulterant in the mixture is an indication as to whether or not the mixture is homogenously mixed or the reaction is complete. Smith does not specifically disclose a step of obtaining  $(dS1/dt)/S1$ , but it would have been obvious to one having ordinary skill in the art at the time the invention was made to calculate the  $(dS1/dt)/S1$  value since during inspection, all of the variables, such as the absorbance measurements at 30 second intervals are recorded from the automatic analyzers to determine the change in absorbance throughout the process of mixing the urine and reagent.

11. Regarding claim 11, the reference Smith discloses the claimed invention. Smith discloses that in the instant invention, when urine which has been adulterated, resulting in an increase in absorbance, is mixed the reagent system in the prescribed ratio, the indicator will cause the sample mixture to increase in absorbance, depending on whether the adulterant is present or not (see column 4, lines 18-27). It is interpreted by the examiner that the reaction is considered to be complete when there is not any adulterant in the reagent to increase the absorbance when being analyzed.

12. Regarding claim 12, the reference Smith discloses a method for detecting an adulterant in urine. In the method of detecting gluteraldehyde adulterant in a sample of urine, an aliquot of urine is inserted into an automatic analyzer and a spectrophotometric absorbance reading is taken. The aliquot is then mixed with a reagent mixture, in a specified ratio, containing an indicator and a second spectrophotometric absorbance reading is taken and compared to the first reading. When the spectrophotometric absorbance is taken, the sample is injected into a series of three instruments where it is automatically analyzed and sample absorbance readings are taken at 405 nm at 30 second intervals. When the mixture is analyzed by the Olympus AU5000 the concentration of the mixed urine and reagent are measured at the wavelength of 405 nm with a sample volume of 10  $\mu$ L and reagent volume of 300  $\mu$ L. Furthermore, when the urine is adulterated, the result is an increase in the absorbance when it is mixed with the reagent system in the specified ratio and the indicator will cause the mixture to increase in absorbance, depending on the presence of the adulterant or not. This inspection of the liquid is done by automatic analyzers which employ spectrophotometric means of inspection (see abstract, column 2, line 65-column 3, line 3, column 4, line 2-column 5, line 51). It is interpreted by the examiner



that the when the analyzer detects the absorbance of the mixed urine and reagent and indicates the increase or no change in the absorbance due to the presence or absence of the adulterant in the mixture is an indication as to whether or not the mixture is homogenously mixed or the reaction is complete. Smith does not specifically disclose a step of obtaining  $(dS1/dt)/(S1-S0)$ , but it would have been obvious to one having ordinary skill in the art at the time the invention was made use the values that were obtained from the first absorbance reading and the continuous absorbance readings at 30 second intervals to calculate  $(dS1/dt)/(S1-S0)$  to determine change in optical absorbance changes over the time the urine and reagent indicator were mixing taking into account the first absorbance reading to normalize the change within the 30 second interval time that is predetermined by the specification parameters of the analyzer.

13. Regarding claim 15, the reference Smith discloses the claimed invention. Smith discloses that in the instant invention, when urine which has been adulterated, resulting in an increase in absorbance, is mixed the reagent system in the prescribed ratio, the indicator will cause the sample mixture to increase in absorbance, depending on whether the adulterant is present or not (see column 4, lines 18-27). It is interpreted by the examiner that the reaction is considered to be complete when there is not any adulterant in the reagent to increase the absorbance when being analyzed.

***Allowable Subject Matter***

14. Claims 9-10 and 13-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. A method for determining homogenization and/or reaction completion where a step of mixing a second reagent to the test liquid and already first liquid that has been optically measured is not found in the prior art.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE T. MUI whose telephone number is (571)270-3243. The examiner can normally be reached on Monday-Thursday 7-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CTM

/Walter D. Griffin/  
Supervisory Patent Examiner, Art Unit 1797